

REMARKS

In the specification, Example 5 has been amended to correct minor typographical error.

Claim 34 has been canceled without prejudice. Claims 30, 32, 33, 35, 37, 39 – 41 have been amended. Claims 28 – 33, 35 – 41 are now pending.

The Applicants reserve the right under 35 U.S.C. §121 to file divisional applications directed to the non-elected subject matter, or applications claiming priority from this application.

35 U.S.C. §112 Rejections

Claims 30, 32 - 33 and 39 - 41 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner states that: (i) claim 30 “is indefinite for not first spelling out full terms followed by their abbreviation in parenthesis. Specifically the terms “BHA” and “TBA” ”; (ii) claims 32 - 33 “are not independent claims and do not recite the claim on which they depend”; and (iii) claims 39 - 41 “depend from a canceled claim”. Office Action, page 2.

Claims 30 and 37 have been amended to recite “butylhydroxyanisole (BHA), thiobarbituric acid (TBA)”. Butylhydroxyanisole (BHA) is an antioxidant consisting of a mixture of two isomeric organic compounds, 2-tert-butyl-4-hydroxyanisole and 3-tert-butyl-4-hydroxyanisole. Support for butylhydroxyanisole can be found at Example 5 where the composition contains tert-butylhydroxyanisole.

Thiobarbituric acid (TBA) is widely used as an antioxidant and the abbreviation is unambiguously understood by anyone skilled in the art. For example, TBA assay is frequently used to determine antioxidant properties (see, Food Res., 23, p.620 (1958)).

Claims 32, 33 and 39 – 41 have been amended to recite the claim on which they depend.

No new matter has been introduced with this amendment. It is respectfully submitted that, in view of these amendments, the claims are not indefinite under 35 U.S.C. §112, second paragraph, and the rejections should be withdrawn.

35 U.S.C. §103(a) Rejections

Claims 28 - 31, 34 - 38 and 40 - 41 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,223,285 to DeMichele (hereinafter “DeMichele”).

Claims 28 - 38 and 40 - 41 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,077,828 to Abbruzzese (hereinafter “Abbruzzese”).

Claims 39 - 41 are rejected under 35 U.S.C. §103(a) as being unpatentable over DeMichele or Abbruzzese in view of U.S. Patent Publication No. 2002/0034562 by Sundram (hereinafter “Sundram”) or U.S. Patent Publication No. 2006/0111254 by Makadia (hereinafter “Makadia”).

It is respectfully pointed out that, contrary to the Examiner’s assertion, it would not have been obvious to modify DeMichele or Abbruzzese. The prior art references cited by the Examiner do not teach or suggest all of the claim limitations, nor would there have been any reasonable expectation of success when the references were modified. Specifically, the pending claims of the present invention require ALA, DHA and EPA at specific weights or percentages, which are unexpected in view of the prior art and are critical to the properties of the present invention.

I. DeMichele

The Examiner states that “DeMichele teaches pharmaceutical compositions comprising ALA, EPA, DHA, vitamin E and gamma LA (abstract). The reference does not teach the compositions with the claimed amounts of each component. However in following the general tone of the reference, it would have been obvious to one of ordinary skill in the art to optimize the various amounts of each component as they are all identified as active components, or result effective variables. Thus, at the time of the claimed invention one of ordinary skill in the art would have been motivated by the cited reference to optimize the amounts of the various components with a reasonable expectation for successfully obtaining an effective pharmaceutical composition”. Office Action, page 3.

Contrary to the Examiner's assertion, it would not have been obvious for one of ordinary skill in the art to discover the claimed ranges through routine experimentation. The percentage ranges in DeMichele are substantially different from the claimed ranges. Specifically, the pending claims require about 53 - 66.7% (w/w) of ALA, and about 13.3 - 20% (w/w) of DHA. In contrast, DeMichele teaches 2.7 - 3.7% (w/w) of ALA, and 2.1 - 2.9% (w/w) of DHA (DeMichele, claims 5 and 26, and Table 5 (col. 13)). One of ordinary skill in the art reading DeMichele and engaged in routine experimentation would not have logically gone far beyond the ranges of ALA and DHA as disclosed in DeMichele. Nor would there have been any reasonable expectation of success when DeMichele was modified. Therefore, it is the Applicants' position that the claimed ranges are unexpected, and thus, are not obvious over the teachings of DeMichele.

This conclusion is supported by experimental evidence showing that a composition having a fatty acid formulation similar to that described and claimed in the present application has significantly improved cardio-protective capabilities (Exhibit A). In the article, the cardio-protective effects of a variety of formulations having fatty acids at different percentage ranges were compared. Mixalpha formulation, which contains ALA, DHA and EPA at very similar percentage ranges as those of the described and claimed (see Table 1 of the article in Exhibit A¹), demonstrated significantly superior cardio-protective effects in comparison to the other fatty acid formulations. These results substantiate the criticality of the claimed ranges. MPEP §2144.05 notes that if there is evidence indicating that the claimed ranges are critical, the claimed ranges are not obvious. Therefore, the present invention is not obvious over DeMichele.

Additionally, unlike the present invention, the major components of the DeMichele compositions are not ALA or DHA. Rather, the most abundant components of the DeMichele compositions are oleic acid (20.8 - 28.2% (w/w)) and linoleic acid (13.5 - 18.3% (w/w)) (DeMichele, Table 5). The abundance of oleic acid and linoleic acid, as well as the small percentages of ALA and DHA, is essential in the teachings of DeMichele. Indeed, DeMichele concludes after the "Experiment" section:

¹ Please note in Table 1 of Exhibit A, C18:3 ω 3 is ALA; C20:5 ω 3 is EPA; and C22:6 ω 3 is DHA.

In view of the foregoing experimental results and detailed comparisons of various lipid blends it was determined that a liquid nutritional product in accordance with the present invention should contain a lipid blend having a fatty acid profile which has, as a % by weight of total fatty acids, the amounts of certain selected fatty acids set forth in Table 5. (DeMichele, col. 13, lines 19 – 25. Emphasis added.)

Furthermore, it was determined that a liquid nutritional product in accordance with the present invention should contain a lipid blend in which: the ratio of n-6 to n-3 fatty acids is in the range of about 1.5 to about 3.0, preferably about 1.72; the ratio of Linoleic acid (18:2n6) to Alpha-Linolenic acid (18:3n3) is in the range of about 3.0 to about 10.0, preferably about 4.96; and the ratio of the sum of EPA and DHA to GLA is in the range of about 1.0 to about 10.0, preferably about 1.64. (DeMichele, col. 13, lines 45 -54. Emphasis added.)

In contrast, as currently claimed, the most abundant components of the present invention is ALA, but not oleic acid or linoleic acid. If the abundance of oleic acid and linoleic acid, as well as the small percentages of ALA and DHA, is essential in the teachings of DeMichele, it would not have been obvious for a person of ordinary skill in the art to modify DeMichele to result in the claimed invention.

II. Abbruzzese

The Examiner states that “Abbruzzese teaches pharmaceutical compositions comprising ALA, EPA, DHA, vitamin E (abstract) and gamma LA (col.5). The reference does not teach the compositions with the claimed amounts of each component. However in following the general tone of the reference, it would have been obvious to one of ordinary skill in the art to optimize the various amounts of each component as they are all identified as active components, or result effective variables. Thus, at the time of the claimed invention one of ordinary skill in the art would have been motivated by the cited reference to optimize the amounts of the various components with a reasonable expectation for successfully obtaining an effective pharmaceutical composition”. Office Action, page 4.

Contrary to the Examiner’s assertion, it would not have been obvious for one of ordinary skill in the art to discover the claimed ranges through routine experimentation. The percentage ranges in Abbruzzese are substantially different from the claimed ranges.

Specifically, the pending claims require about 53 - 66.7% (w/w) of ALA, about 5.3 - 6.7% (w/w) EPA, and about 13.3 - 20% (w/w) of DHA. In contrast, Abbruzzese teaches 2.21% (w/w) of ALA, 17.74% (w/w) of EPA, and 7.73% (w/w) of DHA (Abbruzzese, Table 2 (col. 8)). One of ordinary skill in the art reading Abbruzzese and engaged in routine experimentation would not have logically gone far beyond the ranges of ALA and DHA as disclosed in Abbruzzese, and in the mean time have decreased the percentage of EPA as disclosed in Abbruzzese. Nor would there have been any reasonable expectation of success when Abbruzzese was modified. Therefore, it is the Applicants' position that the claimed ranges are unexpected, and thus, are not obvious over the teachings of Abbruzzese.

Furthermore, as pointed out above, the claimed ranges are critical for the properties of the present invention, which is evident from the scientific article in Exhibit A. Therefore, the present invention is not obvious over Abbruzzese.

Additionally, unlike the present invention, the major components of the Abbruzzese compositions are not ALA or DHA. Rather, the most abundant components of the Abbruzzese compositions include caprylic acid (10.35% (w/w)) and oleic acid (15.23% (w/w)) (Abbruzzese, Table 2). Therefore, it would not have been obvious for a person of ordinary skill in the art to modify Abbruzzese to result in the claimed invention.

III. DeMichele or Abbruzzese in view of Sundram or Makadia

The Examiner states that although DeMichele and Abbruzzese do not teach the claim limitations of claims 39 - 41, Sundram and Makadia cure this deficiency. Office Action, pages 4 - 5.

The Applicants respectfully submit that, for the reason discussed above, it would not have been obvious to modify DeMichele or Abbruzzese. Accordingly, one of ordinary skill in the art would not be motivated to combine DeMichele or Abbruzzese with Sundram and Makadia.

CONCLUSION

Given the foregoing, Applicants respectfully submit that all pending claims are in condition for allowance. Favorable action is earnestly solicited.

Respectfully submitted,
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